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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Anke Esperester et al) Art Unit: 1614
U.S. Appln. No. : 10/677,967) Examiner: To be assigned
Confirmation No. : 9274
U.S. Filing Date : October 2, 2003
Title of Invention : Ambroxol for the treatment of inflammation in the pharynx
Attny. Docket No. : 1/1556

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

March 2, 2005

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

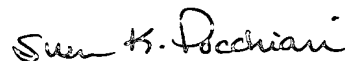
☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,



Susan K. Pocchiari
Attorney for Applicant(s)
Reg. No. 45,016

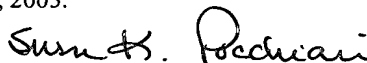
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on March 2, 2005.



Susan K. Pocchiari, Reg. No. 45,016

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/677,967
Filing Date	October 2, 2003
First Named Inventor	Anke Esperester et al
Art Unit	1614
Examiner Name	To be assigned
Attorney Docket Number	1/1556

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		MONTANDON J.B. ET AL; In-Vitro versus in-vivo activities of new 5-Lipoxygenase Inhibitors with Antiinflammatory Activity; Int. J. Tissue Reac. Vol. 11 No. 3 pages 107-112 (1989); Bioscience Ediprint Inc.	
		PIETRO GHEZZI ET AL; Differential Contribution of R and S Isomers in Ketoprofen Anti-inflammatory Activity: Role of Cytokine Modulation 1; The Journal of Pharmacology and Experimental Therapeutics Vol. 287 No. 3 pages 969-974 (1998); The American Society for Pharmacology and Experimental Therapeutics	
		MASAYUKI AIHARA ET AL; Effects of N-Acetylcysteine and Ambroxol on the Production of IL-12 and IL-10 in Human Alveolar Macrophages; Respiration (2000) Vol. 67 pages 662-671; Karger AG Basel	
		M. BIANCHI ET AL; Ambroxol inhibits interleukin 1 and tumor necrosis factor production in human mononuclear cells; Agents and Actions (1990) Vol. 31 pages 275-279; Birkhauser Verlag. Basel	
		S. PFEIFER ET AL; Reduction of Cytokine Release of Blood and Bronchoalveolar Mononuclear Cells By Ambroxol; European Journal of Med. Res. (1997) Vol. 2 pages 129-132; I. Holzapfel Publishers	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.